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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|-------------------------|---------------------|------------------|
| 10/798,023 | 03/11/2004 | Stefan Petersson | PN0103 | 6027 |
| 7590 02/24/2006 | | , | EXAMINER | |
| Amersham Health, Inc. | | | JUNG, WILLIAM C | |
| IP Department 101 Camegie Ce | enter | ART UNIT | PAPER NUMBER | |
| Princeton, NJ 08540 | | | 3737 | |
| | | DATE MAILED: 02/24/2006 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | Application No. | Applicant(s) | | | | |
|--|--|------------------------------------|--|--|--|--|
| | 10/798,023 | PETERSSON ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | William Jung | 3737 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 11 M | larch 2004. | | | | | |
| | action is non-final. | | | | | |
| 3) Since this application is in condition for allowa | | osecution as to the merits is | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-13</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-13</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/o | r election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examine | er. | | | | | |
| 10) The drawing(s) filed on is/are: a) acc | epted or b) \square objected to by the $\mathfrak l$ | Examiner. | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| dec the attached detailed office action for a list | of the certified copies not receive | ou. | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) | 4) Interview Summary | | | | | |
| Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11032004. | Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate atent Application (PTO-152) | | | | |
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DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

37 CFR 1.105 REQUIREMENT FOR INFORMATION

- 1. Applicant (or the assignee of this application if the assignee has undertaken the prosecution of the application) is required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.
- 2. There are numerous other co-pending applications and issued patents, which disclose and claim very similar and/or identical subject matter. In accordance with 37 CFR 1.105 and MPEP 704.11(a) subsection G, applicant (or the assignee) is respectfully requested to disclose all co-pending applications and related patents (please see the non-exhaustive list below of applications and issued patents that the USPTO believes may be related) and identify the specific claims of

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those applications and/or patents which may present double patenting issues with the instant application claims. This requirement is reasonably necessary to examination because, based on an initial review of the applications, there is a significant degree of overlap in claimed subject matter, thus requiring an analysis of commonality of claimed subject matter to determine patentability under 35 USC 101 double patenting and/or obviousness type double patenting. For example, claims 1-13 of application 10/798,023 differ from claims 1-34 of application 09/609,153 now a US Patent Number 6,466,814 B1 (from here on refer to as '818) in only the obvious variation of applying hyperpolarized MR imaging agent that is dissolved in a solvent. Variation in wording of the claims do not change the scope of the invention in '818 from the current application. Because the applicant (or the assignee) is presumably far more cognizant of the contents of the claims in these applications than any Office staff, and has access to the source documents by which such comparison could be done better than within the Office, it is reasonable to require the applicant to provide the information needed to determine the commonality among the claims.

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Should applicant (or the assignee) believe that Double Patenting exists, then applicant (or the assignee) is invited to file Terminal Disclaimers and/or amend the currently pending claims in the interest of expediting the prosecution of the current application. Applicant (or the assignee) should note that a terminal disclaimer is effective to overcome an obviousness type double patenting rejection, but will not overcome a "same type" double patenting rejection under 35 U.S.C. § 101.

3. Non-exhaustive list of possible related co-pending applications and patents: US 20030157020A1 ((10/386,060)

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US 20040024307A1 (10/395,002)

US 20030212323A1 (10/385,822)

US 6,574,495 B1

US 6,453,188 B1

US 6,311,086 B1

US 6,278,893 B1

4. This requirement is subject to the provisions of 37 CFR 1.134, 1.135 and 1.136 and has a shortened statutory period of 2 months. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 3. Claims 1, 2, and 5-11 are rejected under 35 U.S.C. 102(e) as being anticipated by *Driehuys et al* (US 6,491,895).

Driehuys et al anticipates all claimed features in claims 1, 2, and 5-11.

Claim 1: Driehuys et al discloses a method of contrast enhanced magnetic resonance imaging (MRI) of a sample where the method comprises the steps of administering a hyperpolarized MR contrast agent having non-zero nuclear spin nuclei into said sample (the sample in Driehuys et al is a patient) for fluid dynamic investigations of the vasculature (col. 3,

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lines 37 – col. 4, line 15), exposing said sample or part to the sample to radiation of a frequency selected to excite nuclear spin transitions in said nuclear spin nuclei (col. 6, lines 35-49), and detecting MR signals from said sample using MR pulse sequence method (col. 4, lines 47-58).

Claim 2: Driehuys et al disclose that the contrast agent is administered to investigate the blood flow or vasculature of the patient, which is a definition of angiographic investigation (col. 4, lines 40-45). Driehuys et al also disclose that the pulse sequence is gated to the cardiac volume out cycle, which is the image acquisition is gated to the cardiac rhythm (col. 13, lines 44-54; col. 15, line 57 – col. 16, line 16; col. 13)

Claim 5-11: Driehuys et al further disclose the above method where the hyperpolarized agent includes from the group consisting of ¹H, ³He, ³Li, ¹³C, ¹⁵N, ¹⁹F, ²⁹Si, ³¹P and ¹²⁹Xe.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 3, 4, and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over *Driehuys* et al as applied to claim 1 above, and further in view of *Mugler, III et al* (US 5,245,282).

Driehuys et al substantially disclose all claimed features in claims 3 and 4 as described above. However, Driehuys et al do not teach the use of steady state imaging such as FISP or PSIF. In state of the art in magnetic resonance imaging, the use of FISP or PSIF for steady state imaging is well known to compensate for the flow or motion of the blood in blood vessel (col. 1, line 56 – col. 3, line 29). Therefore, it would have been obvious to on having an ordinary skill in

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the art at the time the invention was made to apply the teachings of Mugler, III et al's steady state imaging such as FISP or PSIF to compensate for the motion as encountered in Driehuys et al's method with hyperpolarized administered to the patient's circulation system.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 20, 2006

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700